

REMARKS

A. Status of the Claims

Claims 1-18 were pending at the time of the Office Action, with claims 2-4, 10-12, and 14 having been previously withdrawn from consideration as being directed to a non-elected invention. Claims 1, 9, and 25 have been amended in the Amendment set forth herein without prejudice or disclaimer. Claims 18, 20, and 21 have been canceled without prejudice or disclaimer. No new claims have been added. Thus, claims 1, 5, 7-9, 13, 15-17, 19, and 23-27 are currently under consideration and presented for reconsideration.

Regarding the Amendments to the claims, claim 1 has been amended to recite that the MUC1 test agent comprises a phosphorylated YEKV site. Claim 25 has been amended to recite that the MUC1 test agent is phosphorylated at a YEKV site. Support for the amendments to claims 1 and 25 can be found generally throughout the specification, such as in the claims as originally filed and Example 5 of the instant specification (p. 41, line 6 – page 42, line 5). Claim 20 has been amended to include a comma that was previously inadvertently deleted from the claim.

B. The Rejections Under 35 U.S.C. §103(a) Are Overcome

Claims 1, 5, 7-9, 13, and 15-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Brent (U.S. Patent 6,004,746) in view of Li (Mol. Cell Biol. 18 (12):7216-7224, 1998), Yamamoto (J. Biol. Chem. 272(19):12492-12494, 1997), and Zrihan-Licht (FEBS Letters 356(1):130-136, 1994). The Examiner argues that the claimed invention would be obvious in view of the teachings of these references. Applicants respectfully traverse.

In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A finding of obviousness requires that “the differences

between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. §103(a). In setting forth a *prima facie* case of obviousness, it is necessary to show “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). In the present case, there is *no prima facie* case of obviousness for the following reasons:

Brent does not disclose MUC1, or any information regarding phosphorylation of a YEKV site in MUC1. Further, as admitted by the Examiner (page 6 of Office Action), Brent does not provide any explicit disclosure pertaining to the elected species, β -catenin.

Li does not remedy the deficiencies of Brent. Li teaches that glycogen synthase kinase 3 β binds to an STDRSPYE site in MUC1 and phosphorylates the serine that is adjacent to a proline. This phosphorylation decreases the binding of MUC1 to β -catenin. Li does not teach or suggest that phosphorylation of a YEKV site increases binding of MUC1 to β -catenin. The Examiner has cited to FIG. 5 of Li as teaching GSK3 β as the test agent. However, there is no information in Li to teach or suggest that the MUC1 test agent equivalent in Li was phosphorylated at a YEKV site. Nor would this be inherent, as it is possible for a YEKV site to not be phosphorylated, and Li teaches that it is phosphorylation of a serine residue that affects interaction of MUC1 with β -catenin.

Yamamoto does not provide any teaching or suggestion concerning a MUC1 test agent phosphorylated at a YEKV site. Rather, it concerns certain studies demonstrating that DF3

(MUC1) binds directly to β -catenin and that the SXXXXXSSL motif in DF3 is responsible for this interaction.

Nor does Zrihan-Licht provide the missing limitation of a MUC1 test agent phosphorylated at a YEKV site. While Zrihan-Licht discloses that MUC1 proteins are “extensively phosphorylated” and that phosphorylation occurs “primarily on tyrosine residues” it does not specifically teach phosphorylation of the YEKV site of MUC1. Abstract. MUC1 protein includes 13 tyrosine residues, and there is no information in this reference or in any of the other references to suggest that this particular tyrosine residue, out of all of the amino acids of MUC1, is critical for binding to β -catenin. Further, Zrihan-Licht teaches that other residues may undergo phosphorylation, including serine residues. P. 131, right col., third para. Still further, Zrihan-Licht teaches that the sequence YEEV is important for interaction with SH2 domain-containing tyrosine kinases, thus teaching away from the importance of a YEKV site. In addition, one of ordinary skill in the art would further be led away from the importance of phosphorylation of a YEKV site because, as discussed above, Li teaches that it is a serine residue that affects interaction of MUC1 with β -catenin and Yamamoto teaches that the SXXXXXSSL motif in DF3 is responsible for this interaction.

In view of the foregoing, it is respectfully submitted that there is no *prima facie* case of obviousness based on Brent in view of Li, Yamamoto, and Zrihan-Licht. There is no rational reason that would have led one of ordinary skill in the art, at the time of the invention, to determine that the YEKV site of MUC1 is critical for binding to β -catenin. Therefore, Applicants respectfully request that the rejection of claims 1, 5, 7-9, 13, 15-17, 19, and 23-27 under 35 U.S.C. §103(a) be withdrawn.

C. The Double Patenting Rejections Are Overcome

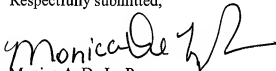
Claims 1, 5, 7-9, 13, and 15-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 7-8 of copending Application No. 10/032,786 (U.S. 2002/0110841 A1). Applicants respectfully traverse.

Applicants understand that this is a provisional rejection only. Applicants will address this rejection, if necessary, once it is no longer provisional.

D. Conclusion

Applicants believe that the foregoing comments are a complete response to the pending Office Action, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-5639 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "monica De La Paz" followed by a stylized flourish.

Monica A. De La Paz

Reg. No. 54,662

Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
Ph. (512) 474-5201
FAX (512) 536-4598

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